

REMARKS

Claims 1-8 and 10-13 are currently pending after this Amendment. Claim 1 has been amended to more particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Non-elected claims 13-34 have been cancelled without prejudice or disclaimer and Applicants expressly reserve the right to file divisional application(s) claiming benefit of 35 U.S.C. 119, 120 and 121.

Reconsideration of the previous rejection of claims 1 and 3-13 under 35 U.S.C. 102(a) and/or (b) as being anticipated by Kohl (U.S. Patent No. 4,758,579) is respectfully requested. Previous Claim 1 recited that the aqueous alkali or alkali earth metal hypohalite solution "has a concentration in the range of 2 to 5%." Such is not found in Kohl which has a sodium hypohalite concentration of 8%. *See* Example 6. No other disclosure supports the claimed 2 to 5% and thus Kohl cannot anticipate Claim 1 or claims dependent thereon. Withdrawal of the rejection is therefore respectfully requested.

Reconsideration of the rejection of Claims 1-8 and 10-13 under 35 U.S.C. 103 (a) is respectfully requested. Kohl is said to teach the claimed invention citing Example 6. However, as noted above Kohl does not teach the 2 to 5% limitation.

Moreover, in comparing Example 6 of Kohl to the recited limitations the following is noted.

1. The work up process of Example 6 is tedious.
2. Isolation should involve use of a phosphate buffer, but the solid did not precipitate after pH adjustment with the phosphate buffer.

3. The use of 2-5% in the claimed process versus the amount in Example 6 of Kohl provides the following results:

### BENZIMIDAZOLE PROCESS – EXPERIMENTAL DETAILS

Repetition of example 6 (US 4758579)	Repetition of example 3 (our application WO 2004/063188)
<p>2-[[[3-methyl-4-(2,2,2-trifluoro-ethoxy)-2-pyridinyl]methyl]thio]-1H-benzimidazole was dissolved in dioxane and sodium hydroxide solution. 8% strength of sodium hypochlorite solution was added dropwise in the course of 2 hours, while cooling to 0-5°C. After addition of sodium thiosulfate solution, the mixture was concentrated to dryness at 30-35°C, the residue was taken up in water and the mixture was brought to pH 7 with phosphate buffer. Gummy mass obtained and the solid could not be isolated.</p>	<p>2-[[[3-methyl-4-(2,2,2-trifluoro-ethoxy)-2-pyridinyl]methyl]thio]-1H-benzimidazole was suspended in a mixture of acetonitrile and water and a solution of sodium hydroxide was added. Slowly 4.2% strength sodium hypochlorite solution was added over a period of 4 hours at 5-10°C. The reaction mass was quenched with sodium metabisulphite solution, acetone was charged, pH was adjusted to 7.5-8.0 using dilute acetic acid and the solid obtained was filtered and washed with water.</p>

### BENZIMIDAZOLE PROCESS – EXPERIMENTAL RESULTS BY HPLC

Experiment	% of Lansoprazole	% of sulphone at RRT 1.08	% of sulphide at RRT 1.26	% of impurity at RRT 1.13	% of impurity at RRT 1.17	% of impurity at RRT 1.21	% of impurity at RRT 1.42	% of total impurities
As per our application	96.9	0.26	0.19	1.14	0.61	0.1	NIL	3.1
As per '579 patent	81.0	0.183	0.06	4.74	4.71	2.71	4.72	19.0

Thus, Kohl does not teach the claimed process and modification with the secondary reference Rainer (U.S. Patent 4,555,518) does not cure this deficiency of Kohl. Withdrawal of the rejection is therefore respectfully requested.

Reconsideration of the rejection of claims 1-8 and 10-13 under 35 U.S.C. 112 first paragraph is respectfully requested. The Examiner argues that there is no compliance with the "written description requirement" of 35 U.S.C. 112 first paragraph. This is incorrect. The specification is replete with written description supporting the claim. *See* for example, Page 5, second paragraph; Page 6, first paragraph, Page 7, first paragraph and Page 8, last paragraph. Withdrawal of the rejection is therefore respectfully requested.

Reconsideration and withdrawal of the rejection of Claims 1-8 and 10-13 under 35 U.S.C. 112, second paragraph, is requested. "Converting" is a term commonly utilized in the chemical arts and is neither vague nor indefinite.

For all of the foregoing reasons, Applicants respectfully request withdrawal of all rejections and passage of the application to issue.

Respectfully submitted,



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Date: July 30, 2006